

LUD 5466.4 CIP - JEL/NDH

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cont

Claim 86: The composition of claim 85, wherein said at least one additional polypeptide has an amino acid sequence consisting of the amino acid sequence set forth in SEQ ID NO: 8, 9 or 10.

Claim 87: The isolated polypeptide of claim 74, consisting of an amino acid sequence set forth in SEQ ID NO: 1.

REMARKS

Applicants wish to thank the examiner for the courtesy extended to their representatives during the December 11 telephone interview. This interview is believed to have been extremely helpful in addressing the pending issues.

Claims 82 and 83 have been cancelled, and replaced by claims 85 and 86, which are believed to address the rejection under 35 USC § 112, second paragraph, at point 10 of the office action. Claim 87 is drawn to subjection matter described in the specification. SEQ ID NO: 1 presents, *inter alia*, the amino acid sequence of NY-ESO-1, which is discussed in the application.

Applicants are also submitting the front page of U.S. Patent No. 6,251,603, "Method For Determining Status of A Cancerous Condition By Determining Antibodies to NY-ESO-1 In A Patient Sample." Only the first page is being submitted in order to minimize the size of this telefaxed response. If the examiner requests a complete copy it will be sent; however, it is believed that the examiner can access the patent via PTO records.

The patent is cited to show that ESO-1 is known to be processed, in vivo, into peptides which complex with Class-II molecules. Were this not the case, antibodies would not be generated, in vivo, and there would be no response to the assays that are clearly enabled. Hence, ESO-1 is clearly a protein processed to Class-II presented peptides.

In the course of the interview, the written description rejection was discussed. Applicants pointed out that the motif they describe as being essential to HLA-DR53 binding was, in fact, established by Futaki, et al., *Immunogenetics* 42:299-301 (1995). It was established that Futaki, et al., is of record.

Review of Futaki, et al. will show that many peptides are described which are shorter than those claimed, but which do, in fact, satisfy the binding motif for HLA-DR53 binding. See, e.g., Table 1 of Futaki, et al. It should also be noted that apart from the recited binding motif, there is no pattern to the sequences of the binding peptides.



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LUD 5603 JEL/MD4

(12) **United States Patent**
Jäger et al.(10) **Patent No.:** **US 6,251,603 B1**
(45) **Date of Patent:** **Jun. 26, 2001**(54) **METHOD FOR DETERMINING STATUS OF
A CANCEROUS CONDITION BY
DETERMINING ANTIBODIES TO NY-ESO-1
IN A PATIENT SAMPLE**(58) **Field of Search** 435/6.7, 91.1,
435/91.2, 183, 810, 287.2; 436/501, 94;
530/388.1, 324, 387.1, 350; 536/23.1, 23.5,
24.31, 24.33(75) **Inventors:** **Elke Jäger, Frankfurt am Main (DE);
Ellsabeth Stockert; Lloyd J. Old, both
of New York, NY (US); Alexander
Krueth, Frankfurt am Main (DE)**(56) **References Cited****U.S. PATENT DOCUMENTS**(73) **Assignee:** **Ludwig Institute for Cancer
Research, NY (US)**5,804,381 9/1998 Chen et al. .
5,811,519 9/1998 Lethe et al. .(*) **Notice:** Subject to any disclaimer, the term of this
patent is extended or adjusted under 35
U.S.C. 154(b) by 0 days.**FOREIGN PATENT DOCUMENTS**

WO 9814464 4/1998 (WO) .

(21) **Appl. No.:** **09/359,503**(22) **Filed:** **Jul. 23, 1999***Primary Examiner*—Bradley L. Sisson(74) *Attorney, Agent, or Firm*—Fulbright & Jaworski, LLP**Related U.S. Application Data**(57) **ABSTRACT**(63) Continuation-in-part of application No. 09/165,546, filed on
Oct. 2, 1998, which is a continuation-in-part of application
No. 09/062,422, filed on Apr. 17, 1998, which is a continu-
ation-in-part of application No. 08/937,263, filed on Sep. 15,
1997, which is a continuation-in-part of application No.
08/725,182, filed on Oct. 3, 1996, now Pat. No. 5,804,381.The invention relates to methods for determining tumor
status by determining antibodies specific to NY-ESO-1 in
patient samples. One can determine whether a cancerous
condition is progressing, regressing, or remaining stable by
determining antibodies against NY-ESO-1 in a patient
sample, and comparing the value obtained to a prior value.
When the tumor in question expresses NY-ESO-1, a change
in this value is indicative of a change in status of the
cancerous condition.(51) **Int. Cl.** ⁷ **C12Q 1/68; C12P 19/34;
G01N 33/566; C07H 21/04; C07K 16/00**
(52) **U.S. Cl.** **435/6; 435/7; 435/91.2;
435/287.2; 436/501; 536/24.33; 530/350;
530/387.1****21 Claims, 3 Drawing Sheets**